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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,171	06/06/2001	Jan F.A. Smits	CU-2481 RJS	6517

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EXAMINER

LUCCHESI, NICHOLAS D

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,171

Applicant(s)

SMITS, JAN F.A.

Examiner

Denise M Pothier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Summary

1. On November 8, 2002, an office action was sent to Applicant rejecting claims 1-5 and objecting to claims 6-10. Applicant responded on 2-17-03, amending claims 1-10.

With regards to the 35 USC 112, 2nd paragraph rejection, Applicant has responded by including an Exhibit A of the metatarsal joint. This figure appears to show the location of the metatarsal joint as the connection between the proximal phalanx of the great toe (B) and the shaft of the first metatarsal (C). (See attached page 69 of Bones and Joints – A Guide for Students, 3rd Edition.) For purposes of examination, an assumption that this is the metatarsal joint referred to in the claims will be made.

Claim Objections

2. Claim 10/1 is objected to because of the following informalities: the distal pad is not recited in claim 1 and raises concerns about its dependency. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Day. See paragraph 15 of the previous office action. To elaborate, Day discloses a first

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point located on the medial side of the big toe (around 10 in Fig. 3), a second point on the lateral side of the big toe (around 48 in Fig. 3) and a third point located on the ball of the foot (see around 10 in Fig. 4 and Fig. 3 shows show part of 24 extends into the phalange region distal to any tarsal joints). The strap 36 in connection with these portions of the Day device facilitates in creating the three point level means as recited.

As for claim 10/1-3, Day discloses in Figures 1, 5 and 8 that the distal pad carries a strap (46) to be located around the big toe.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 and 6,8-9/1-3, as broadly as recited, are rejected under 35 U.S.C. 103(a) as being unpatentable over Baltor (2,471,997) in view of DeRidder (5,730,154). Baltor discloses in Figures 1-3 a brace comprising a three point lever means designed to be located distally of a metatarsal joint, wherein the three points of sized and configured such that one point is located on the medial side of the first phalanx (see 10 in Fig. 1), a second point is located on the lateral side of the distal end of the big toe (see 16 in Fig. 2) and a third point is located on the ball of the foot (bottom region of at least 12 shown in Fig. 2). In addition, Baltor discloses that the device can be made from plastic or other stiff resilient and flexible resilient materials (col. 1, l. 47-49 and col. 2, l.

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6-8) but not from steel wire and pads. DeRidder teaches in column 3, lines 11-14 that is known in the orthopedic art to select from different resilient and flexible materials, including steel or plastic, in order to provide a stiff yet resilient and flexible material. Thus, one having ordinary skill in the art would have known to make the Baltor device from various materials, including substituting steel for the plastic of the Baltor device, in order to produce a device that is stiff, yet resilient. As for selecting to make the Baltor device from steel wire and pads, one having ordinary skill in the art would have been motivated to select from numerous steel constructions, including wire and pads, in order to produce the stiff, yet resilient device of Baltor.

As for claims 2-3, Baltor discloses a proximal pad (right portion of 11 in Fig. 2) pressing on the first phalanx of the big toe (see Fig. 1), a distal pad (16 in Fig. 2) pressing on the distal end of the big toe and the first phalanx (see Fig. 1) and lever arm (region on the bottom and left of 11 in Fig. 2, such as and including portion to the right of 12a in Fig. 2) pressing on the ball of the foot. If the elected structure of Baltor above is not viewed as separate structure, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make each of separate structure, since it have been held that constructing a formerly integral structure in various elements involves only routine skill in the art and making the each element separately makes for easier assembly and does not destroy the function of the Baltor device.

As for claim 8-9/1-3, Baltor discloses a strap (a thin plastic band 12 used for fastening an object into position) provided for fitting around the third toe and made from

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plastic (see col. 1, l. 37). See also the above discussion of Baltor if the strap is not viewed as separate structure.

7. Claims 1 and 7/2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baltor in view of Beeman (3,595,225) and Nakamura (6,027,467). See the above discussion of Baltor with respect to claims 1-3. Baltor does not disclose the lever arm is provided with a silicone tube. Beeman teaches in column 3, lines 3-6 and 20-27 that it is known to coat body supports made from plastic with rubber or other suitable material to allow for prolonged contact with the skin without irritation. As such, one skilled in the art would have known to coat or provide the lever arm with a tubing made from rubber or other suitable material in order to provide prolonged contact without skin irritation. Beeman does not teach using silicone. Nakamura teaches in column 2, lines 59-63 that silicone is an optimal material to have close to the skin for a prolonged period without skin irritation. Thus, one having ordinary skill in the art would have been motivated to use silicone as the tubing over the lever arm of the Baltor device in order to use an optimal material to prevent skin irritation during prolonged periods of use.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dieterich (4,263,902) disclose the state of the art devices for treating hallux valgus. Piper (3,724,458) and Lockhart (5,154,692) disclose the state of the art of toe braces.

Response to Arguments

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9. Applicant's arguments filed 2-27-03 have been fully considered but they are not persuasive. Applicant argues that Day has three pressure points, two of which are located at the metatarsus and thus fails to meet the limitations of claim 1. Remarks on page 3. The Examiner disagrees. Day discloses many pressure points some of which are located in the region of metatarsal joints. However claim 1 is not limited to only three pressure points and Day discloses a structure that comprises a three point lever means as broadly as recited in claim 1. As described above Day discloses a three-point lever means configured to be located in the recited regions of the foot and distal to any metatarsal joint.

Conclusion

10. With regards to the amendments of claims 6-10, Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise M Pothier whose telephone number is (703) 308-0993. The examiner can normally be reached on Monday -Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



Denise Pothier
April 20, 2003